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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,969	04/11/2002	Bang Luu	211815US0	9550

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EXAMINER	
MITCHELL, GREGORY W	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,969	LUU ET AL.	
	Examiner	Art Unit	
	Gregory W Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/02/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the remarks and amendments filed October 25, 2004. Claims 1-9 have been cancelled. Claims 10-29 have been added. Claims 10-29 are pending and are examined herein.

Priority

This Application is a national stage application of PCT/JP00/00742, filed February 10, 2000, and claims foreign priority to JP 11/33312, filed February 10, 2000, and JP 11/180546, filed June 25, 1999. Applicant's priority is acknowledged.

Claim Objections

Claim 12 is objected to because of the following informalities: the claim refers to a "side claim" which should read a "side chain". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borg (USPN 5447959) in view of each of Girianda-Junges et al. (*Tetrahedron*, 54, 7735-

7748), Luu et al. (USPN 6228893), Pruss (USPN 5731354), and Rosen et al. (*Nature*, 362, 59-62).

Borg teaches the treatment of neuro-degenerative illnesses with derivatives of long-chain fatty alcohols (Abstract, col. 13, lines 17-21). Exemplified are trimethylcyclohexenyl compounds substituted with both saturated and unsaturated branched fatty alcohols (col. 19, line 55-col. 21, line 53). Borg teaches that diseases such as Alzheimer's disease, Parkinson's disease, Huntington's chorea and amyotrophic lateral sclerosis are disorders associated with the progressive disappearance of certain neurons (col. 1, lines 49-53). Borg teaches that the compounds taught therein promote neuronal differentiation as well as survival of neurons (col. 25, lines 55-58). The agents of Borg are taught to be administered as pharmaceutical compositions by various means, preferably orally (col. 15, lines 4-11). Neuro-degenerative disorders are taught to be treatable in dosages of 0.1 mg/kg/day to 10 mg/kg/day (col. 28, lines 8-19). These dosages correlate to 7.0 mg/day to 700 mg/day for an average individual weighing 70 kg. Borg does not specifically teach the treatment of amyotrophic lateral sclerosis, nor does Borg specifically teach the specific fatty alcohol groups as instantly claimed. It is noted, however, that Borg teaches saturated and unsaturated aliphatic chains in general (col. 3, lines 21-22).

Girianda-Junges et al. teaches the cyclohexenes as instantly claimed (p 7736). The cyclohexenes are taught to be small lipids which are able to mimick the biological activity of naturally occurring protein neurotorphic factors which are, in turn, taught as potential therapeutic agents for the treatment of neurodegenerative disorders (p 7735).

The cyclohexenes wherein the straight chain aliphatic substituent is between 10 and 14 carbon atoms were taught to be neurotropic by inducing neurite outgrowth, which is taught to be associated with neuronal differentiation and neuron survival (pp 7736 and 7740).

Luu et al. teaches the cyclohexenes as instantly claimed (col. 2, lines 1-18). The cyclohexenes are taught to be useful for the treatment of disorders such as Alzheimer's disease and dementia (neurodegenerative disorders) (Abstract; col. 2, lines 39-42).

Pruss teaches a fatty alcohol derivative for the treatment of neurodegenerative disorders, including stroke, Alzheimer's disease, multiple sclerosis and amyotrophic lateral sclerosis (col. 4, lines 26-30). The fatty acid alcohol derivatives of Pruss are taught to act as lipids and to treat the neurodegenerative disorders above by inhibiting the degeneration of neural cells leading to premature apoptosis and cell death (col. 4, lines 18-25 and lines 40-49).

Rosen et al. teaches that mutations in superoxide dismutase gene are associated with familial amyotrophic lateral sclerosis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to ~~treat~~ specifically treat amyotrophic lateral sclerosis with the specific compounds of Borg as instantly claimed because (1) Borg teaches that the compounds disclosed therein are useful for the treatment of neuro-degenerative disorders in general; (2) Borg teaches that diseases such as Alzheimer's disease and amyotrophic lateral sclerosis operate via a similar etiology; (3) Luu et al. teaches that the compounds as instantly claimed are useful for treating disorders such as Alzheimer's and dementia

(neurodegenerative disorders); and (4) Pruss teaches that amyotrophic lateral sclerosis and Alzheimer's disease are both neuro-degenerative disorders and that both are treatable by similar means, specifically by a fatty alcohol derivative which acts as a lipid. It is also noted that (1) Borg and Pruss both teach that amyotrophic lateral sclerosis is associated with neuron death; (2) Borg teaches the treatment of neurodegenerative disorders with compounds that encompass the instantly claimed compounds; (3) Pruss teaches that the fatty alcohol derivatives disclosed therein are useful for inhibiting premature apoptosis; and (4) Girianda-Junges et al. teaches that the cyclohexenes as instantly claimed are known to be neurotropic and that such actions are associated with neuron survival. One would have been motivated to specifically treat amyotrophic lateral sclerosis with the compounds as instantly claimed because of an expectation of success in treating various specific neuro-degenerative disorders with fatty alcohol derivatives, as taught by both Borg and Pruss.

It is noted that, as taught by Rosen et al., amyotrophic lateral sclerosis is a disorder associated with a mutation in a superoxide dismutase gene. Accordingly, the treatment of amyotrophic lateral sclerosis is obviously a treatment for a disorder associated with a mutation in a superoxide dismutase gene.

Response to Arguments/Amendments

Applicant's arguments with respect to claims 10-29 have been considered but are moot in view of the new ground(s) of rejection. The arguments are addressed as they pertain to the instant rejections.

Applicant argues, "Girlanda-Junges et al only postulate[s] that cyclohexenoic long-chain fatty alcohols may potentially lead to a viable therapy to alter the pathogenesis of neurodegenerative disorders." This argument is not persuasive because Examiner has not rejected the instant claims over Giranda-Junges et al. individually, but together with Borg and Russ. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is noted, as discussed above, that Borg teaches a genus of compounds that encompasses the instantly claimed compounds for the treatment of neurodegenerative disorders. The teachings of Girlanda-Junges et al. is used only to show that the specific fatty alcohols disclosed therein are specifically known to be neurotropic and that the activitiy associated with said fatty alcohols is also known to be associated neuron survival, as taught by both Girlanda-Junges et al. and Borg (and as discussed above).

Applicant argues that Borg specifically excludes amytrophic lateral sclerosis or a disorder caused by mutation in a superoxide dismutase gene. Examiner is unable to find a specific exclusion in the specification of Borg. It is noted, however, that Borg teaches (1) the treatment of Alzheimer's disease, Parkinson's disease, Huntington's chorea *and other neurodegenerative diseases*; and (2) that diseases such as Alzheimer's disease, Parkinson's disease, Huntington's chorea and amyotrophic lateral sclerosis are the consequence of the progressive disappearance of certain neurons. Accordingly, it is Examiner's position that Borg is meant to encompass the treatment of

amyotrophic lateral sclerosis because Borg teaches the treatment of 3 specific neurodegenerative disorders and neurodegenerative disorders in general and also teaches that amyotrophic lateral sclerosis has a similar etiology to those neurodegenerative disorders specifically recited as treatable by the invention disclosed therein.

Applicant argues, "[a]myotrophic lateral sclerosis is a disease that is pathologically known for its extraordinarily unique behavior ... [and] because of such [un]predictable behavior, there is no teaching or suggestion in either Girlanda-Junges et al. or Borg that amyotrophic lateral sclerosis can be effectively cured by treatment with the compound of the present claims." This argument is not persuasive because, as discussed above, Borg teaches that amyotrophic lateral sclerosis has a similar etiology to other neurodegenerative disorders. It is noted that Pruss also teaches the similarity of treating amyotrophic lateral sclerosis with other neurodegenerative disorders, as discussed above.

It is noted that Applicant's arguments regarding Luu et al. are not persuasive because Examiner relies on Borg and Russ to teach the equivalence of treating Alzheimer's disease and amyotrophic lateral sclerosis with fatty alcohol derivatives, as discussed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER